

# An introduction to research in integrative medicine

Dr Ava Lorenc & Dr John Hughes,  
Research Council for Complementary Medicine



# Introduction

## RCCM:

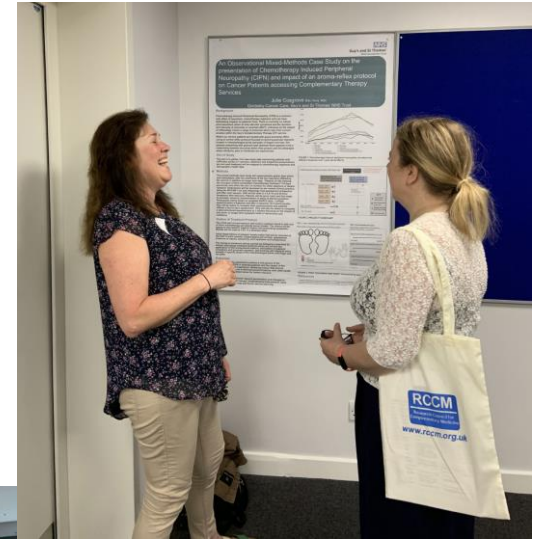
- UK's leading authority on TCIM (Traditional Complementary and Integrative Medicine) research.
- To support, nurture and advise on delivering high-quality research within the TCIM community.
- Trustees
- Members
- Conference

## John Hughes

- Head of Research, Royal London Hospital for Integrated Medicine
- Associate Professor, University of West London
- Co-Chair, RCCM

## Ava Lorenc

- Editor in Chief, EuJIM
- Trustee at RCCM
- Senior Research Associate, University of Bristol



# Overview of session

- Searching for evidence (Ava)
- Critical appraisal (Ava)
- Methodological approaches for studying IM (John)
- Publication and dissemination (Ava)
- What the RCCM can offer (John)



## How to search for and retrieve research papers

- Databases
- Open access journals/papers
- Email author
- Pay per view
- Research Gate
- Copyright

# How to search for and retrieve research papers

## Databases:

- Pubmed/medline: [www.ncbi.nlm.nih.gov/pubmed/](http://www.ncbi.nlm.nih.gov/pubmed/)
- Google scholar: <https://scholar.google.co.uk/>
- Cochrane library: <http://cochranelibrary-wiley.com/cochranelibrary/search>
- AMED
- OVID
- Cinahl (nursing & allied health)
- PsycInfo
- Embase (biomedical)

# How to search for and retrieve research papers

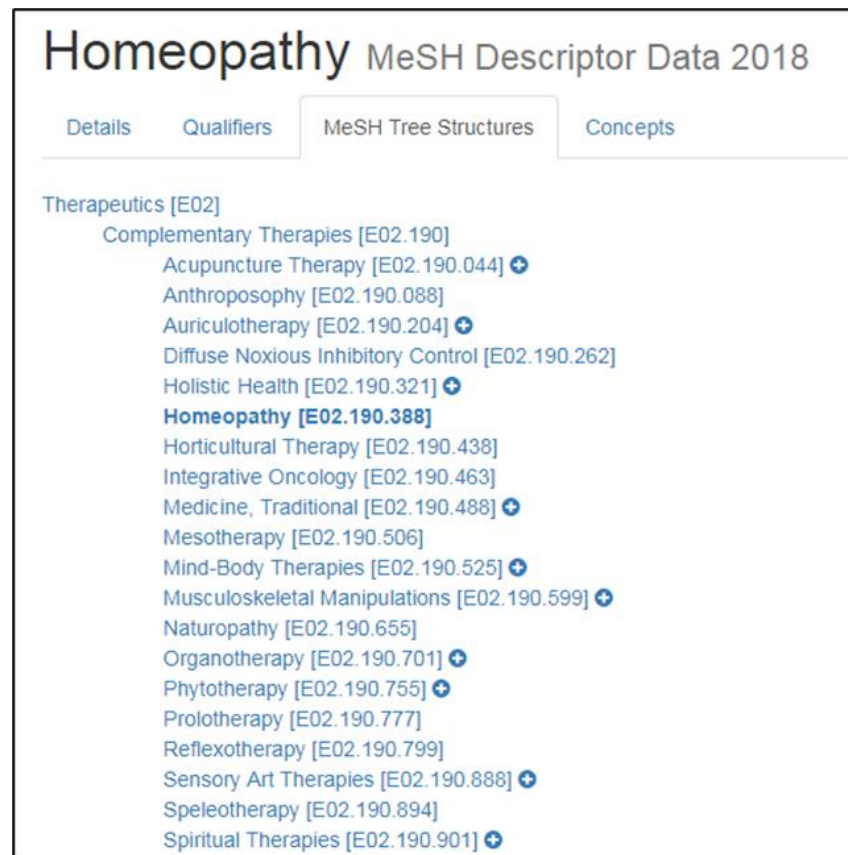
## Other types and sources of literature

- Reference lists
- NHS Evidence
- Citations & related articles – google scholar, article websites
- Grey literature (non journal)
- Protocols
- Conference abstracts
- Registries (for ongoing research) e.g. UKCRN, Health service research projects in progress, Prospero
- Theses (index to theses)

# How to search for and retrieve research papers

## Searching:

- Keyword/search terms – MeSH terms; Advanced Search Results - PubMed (nih.gov)
- Date limits?
- Language limits?
- PICO(TS): population, intervention, comparator, outcomes, timing, and setting.
- Combining search terms



The screenshot shows the MeSH Descriptor Data 2018 interface for Homeopathy. It features a navigation bar with tabs for Details, Qualifiers, MeSH Tree Structures, and Concepts. The MeSH Tree Structures tab is selected, displaying a hierarchical list of Therapeutics [E02]. The list includes Complementary Therapies [E02.190] and its sub-branches: Acupuncture Therapy [E02.190.044], Anthroposophy [E02.190.088], Auriculotherapy [E02.190.204], Diffuse Noxious Inhibitory Control [E02.190.262], Holistic Health [E02.190.321], Homeopathy [E02.190.388], Horticultural Therapy [E02.190.438], Integrative Oncology [E02.190.463], Medicine, Traditional [E02.190.488], Mesotherapy [E02.190.506], Mind-Body Therapies [E02.190.525], Musculoskeletal Manipulations [E02.190.599], Naturopathy [E02.190.655], Organotherapy [E02.190.701], Phytotherapy [E02.190.755], Prolotherapy [E02.190.777], Reflexotherapy [E02.190.799], Sensory Art Therapies [E02.190.888], Speleotherapy [E02.190.894], and Spiritual Therapies [E02.190.901]. Each item in the list has a small plus sign icon to its right.

# Critical appraisal of different study designs

Study type	Reporting checklist	Quality assessment	
RCT	<a href="#">CONSORT</a> (+ extensions) e.g. STRICTA	<a href="#">Cochrane Risk of Bias</a> <a href="#">Jadad</a>	<a href="#">CASP</a> (Critical Appraisal Skills Programme)
Systematic review	<a href="#">PRISMA</a>	<a href="#">AMSTAR 2</a> <a href="#">ROBIS</a>	
Feasibility study	<a href="#">CONSORT</a> + extension		<a href="#">Equator</a>
Qualitative	<a href="#">COREQ</a> <a href="#">SRQR</a> (Standards for Reporting Qualitative Research)		
Protocols	<a href="#">SPIRIT</a>		



# Critical appraisal

- Date of publication
- Country
- Setting (clinical etc)
- Study design
- Quality
- Size of study
- Impact factor of journal



# Critical appraisal

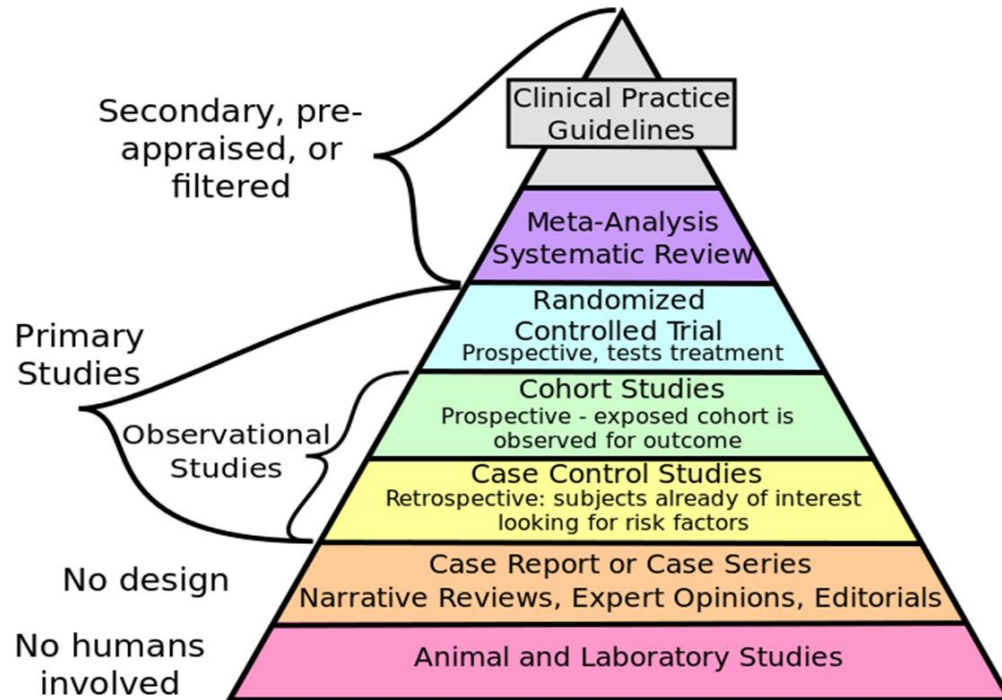
## Key points to look for (RCTs):

- Randomisation (randomisation process, concealment of allocation etc)
- Sample size estimation
- Blinding
- Withdrawals/dropouts
- Publication bias

## Guidance:

- Cochrane handbook
- BMJ EBM Toolkit <http://bestpractice.bmj.com/info/toolkit/ebm-toolbox/>  
includes critical appraisal, statistics, glossary, resources

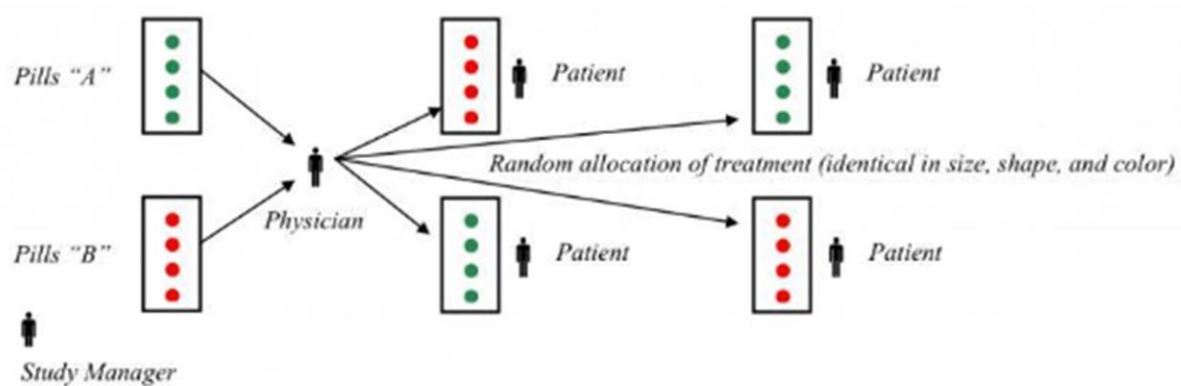
# Methodological approaches for studying integrated medicine



Qualitative research, including meta synthesis

# Methodological approaches for studying integrated medicine

The supposed 'gold standard' of the double blind randomised controlled trial



# Methodological approaches for studying integrated medicine

## Challenges with the RCT design for integrated medicine ‘Model validity’

- The methodological rigour, reliability and relevance of a randomised controlled trial is influenced by factors including its internal validity and external validity.
- One methodological factor which receives comparatively less attention is model validity.
- Model validity describes the degree of concordance between the intervention administered within a trial and the ideal administration of the intervention within normal clinical practice.
- Model validity is particularly relevant in randomized controlled trials of complex interventions, such as integrated medicine.
- If the model validity of a trial intervention is low, this may result in false negative findings: the intervention appears ineffective when in fact the negative findings are the result of suboptimal treatment.

# Methodological approaches for studying integrated medicine

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# Methodological approaches for studying integrated medicine

## Challenges with the RCT design for integrated medicine ‘Model validity’

Author	Population	Design	Treatment administered	Criteria for assessing improvement	Findings
David et al (1999)	56 patients with definite or classical RA, recruited from a hospital based rheumatology outpatient clinic.	Randomised placebo-controlled cross over design. Participants randomly assigned to receive either five weekly treatments of acupuncture or placebo. This was followed by a wash-out period of six weeks, after which each participant received the alternative intervention. The trial was participant and assessor blind.	Acupuncture treatment consisted of LI3 needled bilaterally. The needles were inserted for four minutes and manipulated on two minutes for five seconds.  The placebo treatment consisted of holding a needle introducer on point LI3 for four minutes without pressure or skin puncture.	-Measurement of inflammatory markers (ESR and CRP) -VAS of pain -VAS of patient's global assessment -28 swollen joint count -28 tender joint count -Number of analgesic tablets taken daily -General health questionnaire 28 -Modified Disease activity score (DAS) index	No significant effect from a acupuncture treatment on any of the outcome variables.
Man and Baragar (1974)	20 patients with classical or definite RA for five or more years, seropositive for RF, and in whom pain in both knees was a major problem.	Double-blind randomised controlled trial. Group 1 (ten patients), intra-articular corticosteroids on one knee, other knee treated once with true acupuncture. Group 2 (ten patients) intra-articular corticosteroids on one knee, other knee treated once with sham acupuncture. The study was participant and assessor blind.	True acupuncture consisted of needles inserted at points GB34, SP9, and, S43 and connected to a 6.26 electro-stimulator at 5mA for 15 minutes.  Sham acupuncture consisted of the insertion of three acupuncture needles inserted on the patella of the knee and 5cm above and 5cm below the first needle on the longitudinal line of the leg. Needles connected to a 6.26 electro-stimulator at 5mA for 15 minutes.	-Pain relief at rest, during flexion, extension, weight bearing, and walking on a five point scale -Local heat and swelling -Analgesic intake	Acupuncture effective in relieving pain for up to three months, but had no anti-inflammatory effect.

# Methodological approaches for studying integrated medicine

## Challenges with the RCT design for integrated medicine 'Model validity'

- A review of the trials by both David et al (1999) and Man and Baragar (1974) however, reveals that they appear to have failed to administer a treatment which reflects that administered in clinical practice by any of the acupuncturists, traditional or western, who were interviewed for this study.
- Systematic reviews (and NICE) continue to conclude that acupuncture is ineffective for rheumatoid arthritis, based on trials of interventions with low model validity!

Complementary Therapies in Medicine (2007) 15, 101–108



Complementary  
Therapies in  
Medicine

www.elsevierhealth.com/journals/ctim

### Exploring acupuncturists' perceptions of treating patients with rheumatoid arthritis<sup>☆</sup>

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Available online 3 November 2006

#### KEYWORDS

Acupuncture;  
Acupuncturists'  
perceptions;  
traditional/western  
theoretical base;  
Rheumatoid arthritis;  
Qualitative research;  
Grounded theory  
method

#### Summary

**Aims:** To outline acupuncturists' perceptions of treating patients with rheumatoid arthritis (RA), exploring the impact of practitioner affiliation to a traditional or western theoretical base.  
**Methods:** Qualitative study utilising Grounded Theory Method. Nineteen acupuncturists were chosen via theoretical sampling. In-depth semi-structured interviews were tape-recorded and transcribed. Field notes were also taken. Emerging categories and themes were identified.

**Results:** Inter-affiliatory differences were identified in the treatments administered and the scope and emphasis of intended therapeutic effects. Limited divergence was found between acupuncturists' perceptions of treatment outcomes. Factors perceived as impacting on treatment outcomes were identified.  
**Conclusions:** Clinical trials of acupuncture in RA may have failed to administer a treatment which reflects that administered in clinical practice. Outcome measures employed in clinical trials of acupuncture in RA, as well as established outcome indices for RA, may lack the necessary breadth to accurately assess acupuncture's efficacy. Acupuncturist affiliation has demonstrable implications for the practice and research of acupuncture.  
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#### Introduction

There has been increasing recognition of the impact of choice of outcome criteria on conclu-

sions of efficacy in complementary and alternative medicine (CAM).<sup>1–3</sup> However, little research has been conducted to evaluate the perceived effects or intended therapeutic effect of CAM treatments. Despite ever increasing numbers of clinical trials attempting to evaluate the efficacy of CAM, this dearth of research to inform choice of outcome criteria poses a serious threat to the validity of findings and conclusions of efficacy.

A high prevalence of CAM use has been identified among patients with RA, with acupuncture being

<sup>☆</sup> Sources of support: The corresponding author was in receipt of a Ph.D. studentship with Manchester Metropolitan University when conducting the study.

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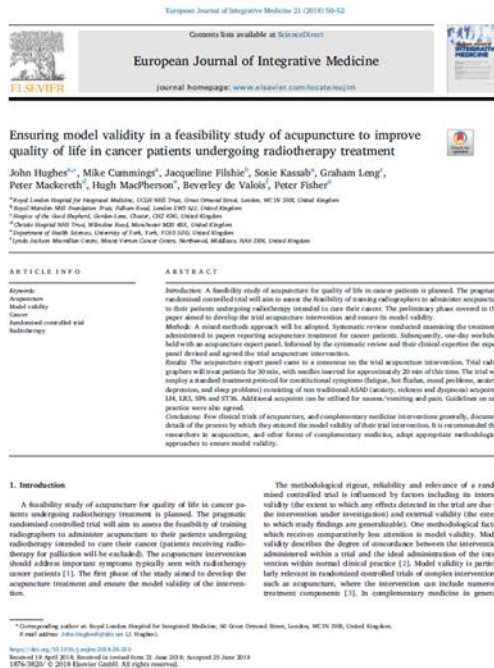


# Methodological approaches for studying integrated medicine

## Challenges with the RCT design for integrated medicine ‘Model validity’

- Integrated medicine trials need to ensure model validity, using appropriate methods.
- For example:

Mixed methods approach adopted. Systematic review conducted examining the treatments administered in papers reporting acupuncture treatment for cancer patients. Subsequently, one-day workshop held with an acupuncture expert panel. Informed by the systematic review and their clinical expertise the expert panel devised and agreed the trial acupuncture intervention.



# Methodological approaches for studying integrated medicine

## Challenges with the RCT design for integrated medicine ‘placebo/control intervention’

- For many integrated medicine approaches there are not any appropriate sham/placebo intervention available for use in a RCT.
- A placebo intervention needs to be indistinguishable from the true intervention, yet physiologically inert.
- For example, in acupuncture ‘placebos’ mostly consist of needles inserted at ‘wrong’ places; retractable ‘stage dagger’ needles, which do not penetrate the skin; or inactivated TENS or placebo medication have been used in some acupuncture trials.

# Methodological approaches for studying integrated medicine

## Challenges with the RCT design for integrated medicine ‘placebo/control intervention’

- Many trial of acupuncture compare two different acupuncture treatments, as opposed to acupuncture versus placebo. IS IT ANY WONDER THEY FREQUENTLY FIND BOTH TREATMENTS ARE EFFECTIVE! BUT WRONGLY CONCLUDE THAT ACUPUNCTURE IS NO BETTER THAN PLACEBO!
- One solution is the pragmatic trial design, which compares the intervention plus standard care, to standard care alone.

# Methodological approaches for studying integrated medicine

## Challenges with the RCT design for integrated medicine 'placebo/control intervention'

- Even in integrated medicine modalities amenable to the randomised placebo controlled trial design, such as herbal or homeopathic interventions, pre trial research needs conducting to ensure the placebo intervention is indistinguishable to the real intervention.

Complementary Therapies in Medicine (2013) 21, 195–199



### A randomised double-blind comparability study of a placebo for Individualised Western Herbal Medicine

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Available online 11 April 2013

**KEYWORDS**  
Individualised  
Western Herbal  
Medicine;  
Placebo;  
Randomised double  
blind comparability  
study

#### Summary

**Objectives:** To determine the non-inferiority of placebo individualised Western Herbal Medicine (IWHM) tinctures compared with true IWHM tinctures.  
**Design:** Randomised double blind comparability study.  
**Setting:** Pharmacy department of an NHS integrated medicine hospital.  
**Interventions:** The IWHM intervention consisted of mixed tinctures of five herbs from a list of eleven herbs for which chronic knee pain is an established indication. Placebo IWHM tinctures contained food and colouring extracts, designed to mimic as closely as possible the taste, smell and appearance of true IWHM.  
**Main outcome measures:** The primary outcome of the study was the proportion of patients who indicated that they believed they were taking true IWHM. Secondary outcomes included the palatability of the true and placebo tinctures.  
**Results:** 64% of the placebo group indicated that they believed they had consumed true IWHM, compared with 60% of the true IWHM group. The palatability of the placebo IWHM was also acceptable to participants, and similar to the palatability of true IWHM.  
**Conclusion:** The findings from the present study indicate that the placebo tinctures were non-inferior to the true IWHM tinctures in terms of participants' ability to correctly identify them as herbal tinctures by their taste, smell and appearance. The placebo tinctures could be utilised in future double blind, placebo controlled randomised trials of IWHM.  
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#### Introduction

The use of herbal interventions for the treatment of medical conditions is widespread. In 2002 the World Health

Organization estimated that up to 80% of people in developing countries rely on herbal medicines for their primary healthcare needs.<sup>1</sup> Within the developed world herbal medicines continue to be a popular treatment option. A recent large UK survey of complementary and alternative medicine use by patients with cancer, for example, found herbal medicine was the most popular treatment modality with 22.3% of patients having consumed one or more herbal medicines since their diagnosis.<sup>2</sup>

The widespread global use of herbal medicines has led to demands for scientific evidence of their efficacy and

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# Methodological approaches for studying integrated medicine

## Challenges with the RCT design for integrated medicine 'outcome measures'

- IF YOU FAIL TO ASK PARTICIPANTS IF THEY EXPERIENCED A CHANGE IN A SPECIFIED OUTCOME, YOUR TRIAL WONT DETECT IT!
- Evidence indicates that many integrated medicine modalities elicit effects which typically go undetected in traditionally employed outcome measures, which were designed to detect the effects of conventional (typically pharmacological) interventions.

# Methodological approaches for studying integrated medicine

## Challenges with the RCT design for integrated medicine ‘outcome measures’

- Development of outcome measures aimed at capturing the wider effects of integrated medicine interventions
  - MYMOP
  - Warwick Holistic Health Questionnaire
- Or utilise a qualitative study within the trial design, to capture patients’ experiences!

# Methodological approaches for studying integrated medicine

## Qualitative research

- Concentrates on how individuals, or groups of individuals, view and understand their world and how they construct meaning out of their experiences.
- Explores the meaning which the phenomena has for the individuals themselves.
- Attempts to gain insight into the processes or factors which influence the phenomena (e.g. why and how certain decisions are made)
- There are a variety of approaches and methods for conducting qualitative research. Some of the main ones are:
  - Thematic analysis
  - Phenomenology
  - Ethnography
  - Grounded theory
  - Narrative
  - Framework

# Methodological approaches for studying integrated medicine

## Qualitative research

- Qualitative studies can detect effects in RCTs not picked up in the trials outcome measures, and provide a much greater understanding of the lived experience.
- **HOWEVER, QUALITATIVE RESEARCH DOES NOT NEED TO BE NESTED IN A TRIAL, AND IS OF VALUE IN AND OF ITSELF.**



# Publication and dissemination of your research

## Why disseminate?

- ✓ Required by funder
- ✓ Research is no use sitting on a shelf!
- ✓ Make an impact
- ✓ Change practice/policy
- ✓ Open discussions
- ✓ Raise awareness

*Research is of no use unless it gets to the people who need to use it*

Professor Chris Whitty, Chief Scientific Adviser for the Department of Health

# Publication and dissemination of your research

## Where to publish?

- Journals
- Magazines/non peer-reviewed journals
- Social media
- Blogs
- Mainstream press
- Lay summary



# Publication and dissemination of your research

## CAM Journals

- EuJIM
- BMC CAM – Open access
- Complementary therapies in clinical practice
- Complementary therapies in medicine
- Journal of complementary and integrative medicine
- Evidence based CAM
- Alternative Therapies in Health and Medicine
- FACT
- Journal of holistic nursing
- Journal of holistic healthcare
- Therapy specific

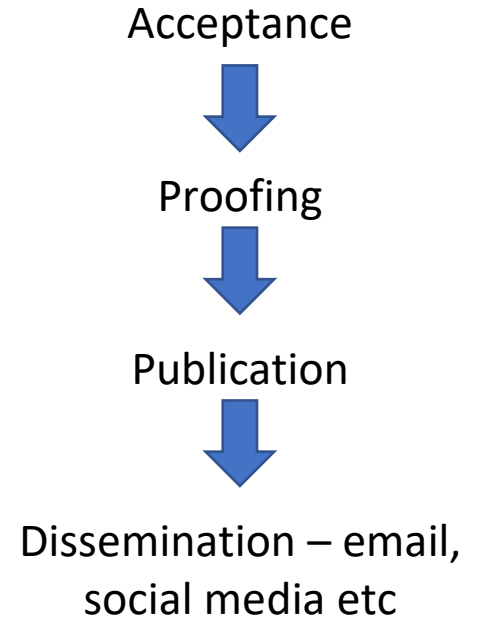
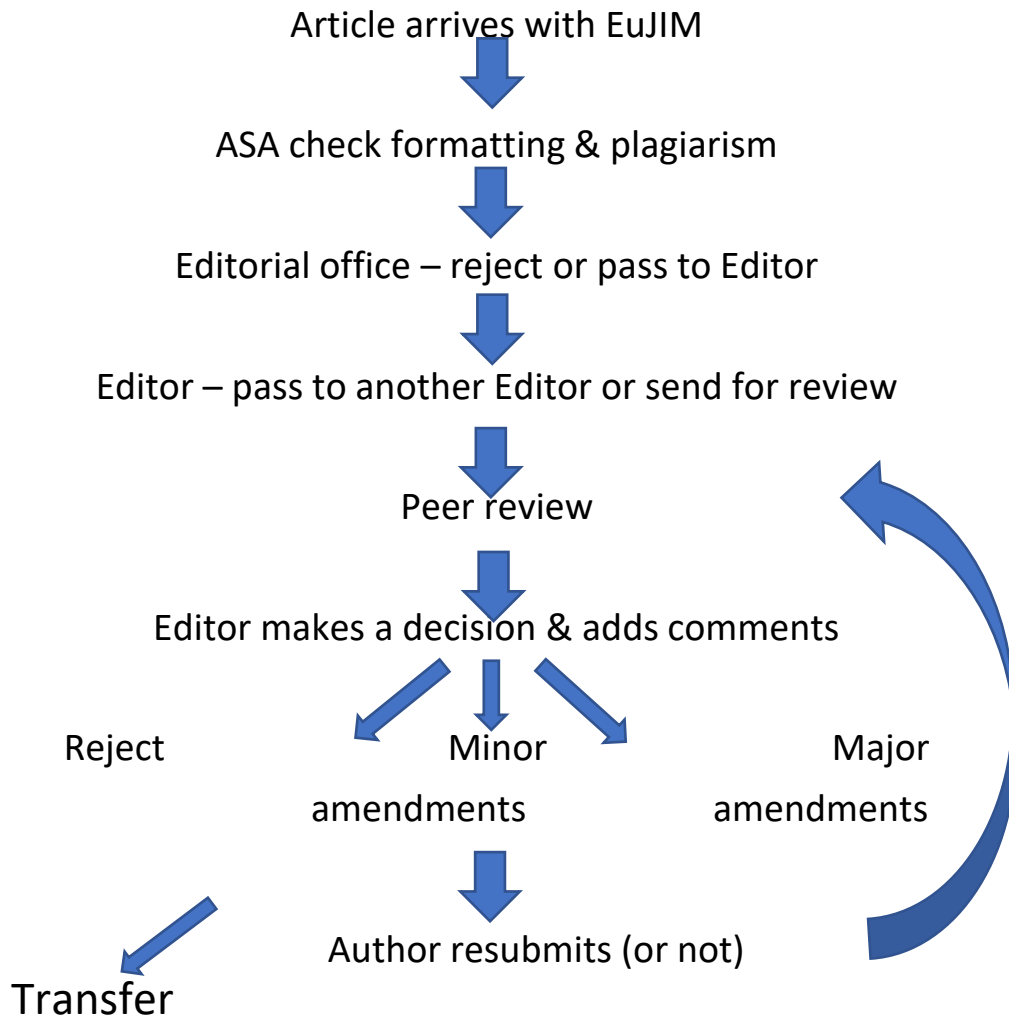


# Publication and dissemination of your research

## Choosing a journal:

- ✓ **Best audience for your message**
- ✓ Open access or pay per view?
- ✓ Scope
- ✓ Impact factor, CiteScore and other metrics
- ✓ Word count
- ✓ Type of papers published
- ✓ Visibility, social media presence etc.
- ✓ Turnaround time





## How not to get rejected

- ✓ Reporting checklists e.g. Consort, Prisma, Coreq
- ✓ Format for the journal
- ✓ Good English, concise
- ✓ Title and abstract are important
- ✓ Likely to be cited
- ✓ Interest to readers

Follow the  
guide for  
authors

Think of  
the  
audience

Anticipate  
reviewers'  
comments

# What can the RCCM offer?

## **RCCM Members:**

### **CAM Research Network Newsletter (free)**

CAMRN membership is free and provides members with access to the CAMRN research network, which provides regular newsletters about conferences, events, projects, funding, new research and dissemination of members queries and requests.

### **Full Member (£50 p/a)**

Full members receive a 10% discount on RCCM events, a quarterly newsletter and access to the subscribers-only sections of the RCCM website including our research map, workshop material, and CAM research and funding resources.



# What can the RCCM offer?

## Corporate Member

This is open to non-commercial organisations involved in the complementary medicine sector. The annual subscription is £200 pa. Benefits include a 10% discount on 2 workshop places per year and a free place to attend the CAMSTRAND conference for a member of your staff. Additional Benefits:

- A greater say in discussions with key stakeholders in the field of integrated medicine such as the IHC parliamentary group, NICE and the Advertising Standards Authority
- A profile on our website, on our dedicated corporate members page to boost your profile and drive traffic to your site
- A logo on your website to promote your membership, establishing your links with credible research.
- A unified voice to continue to advocate for the wider availability and integration of complementary approaches within the NHS.
- Reduced rates for attendance at RCCM events and workshops for your members.
- Exclusive access to additional resources on research and funding, both on our website and personally from our expert base.







# Annual Conference

*Methods for developing the evidence  
within traditional, complementary  
and integrative medicine*

Friday 13th September 2024  
**Online**

The RCCM Conference is a friendly and inclusive event, which particularly welcomes PhD students, postgrads and early career researchers. It will include a mix of poster and oral presentations, a keynote speaker and plenty of opportunities for networking.

### Submit a late-breaking abstract

*Deadline 14th June 2024*

Abstracts on any research in traditional, complementary and integrative medicine are welcome, but particularly those focusing on:

- Methods
- Reflections
- Protocols

Submit your abstract (poster or oral) here:

<https://www.rccm.org.uk/abstract/>

### Who should attend?

- PhD, postgrad and early career researchers with an interest in complementary and integrative medicine, social prescribing, holistic healthcare
- Supervisors
- Researchers
- Practitioners who are interested in getting involved in research

**Register here:**

<https://www.rccm.org.uk/rccm-annual-conference-2024/>



# Recommended reading

- MRC Complex interventions guidance
- CAM and trial design:
  - Mason, S., et al. (2002). "Evaluating complementary medicine: methodological challenges of randomised controlled trials." *BMJ* 325(7368): 832-834.
  - Verhoef, M. J., et al. (2005). "Complementary and alternative medicine whole systems research: Beyond identification of inadequacies of the RCT." *Complementary therapies in medicine* 13(3): 206-212.
- Feasibility studies
  - Eldridge, S. M., et al. (2016). "Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework." *PLoS ONE* 11(3): e0150205.
- Pragmatic trials
  - Macpherson, H. (2004). "Pragmatic clinical trials." *Complementary therapies in medicine* 12(2-3): 136-140.
- Research methods in health by Ann Bowling
- <https://www.bbc.co.uk/programmes/m0004l7k>

